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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,588	03/20/2006	Yuzuru Ishibashi	0152-0727PUS1	2926
2292 7590 05/07/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER MELLON, DAVID C				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/572,588

Applicant(s)

ISHIBASHI, YUZURU

Examiner

DAVID C. MELLON

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/1/2010 has been entered.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1-8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 1-2 and 12 recites the limitation "the cross sectional area of the cylindrical housing". There is insufficient antecedent basis for this limitation in the claim.

Claims 1 and 2 recites the limitation "the longitudinal axis of the nozzle". There is insufficient antecedent basis for this limitation in the claim.

Claims 1 and 2 recites the limitation "said coincident line". There is insufficient antecedent basis for this limitation in the claim. It is unclear if this is the same coincident line recited earlier in the claim or an additional coincident line.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2 and 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haworth et al. (USP Re. 36,125).

Regarding claims 1, 2, and 11, Haworth et al. discloses a hollow fiber bundle wound on a core for radially outward flow of a fluid (Abstract) in figure 1 comprising:

- A hollow fiber membrane bundle formed of a plurality of hollow fiber membranes (70) (the bundle can also be considered rod shaped)
- A housing (12)
- An inlet (26) and an outlet (41, 40), additionally, gas inlet (22) and gas outlet (24)

Furthermore, Haworth et al. discloses a mass transfer device including a hollow fiber bundle wound on a core for radially outward flow (Abstract) wherein the packing fraction of the hollow fibers increases radially outward (C3/L25-43). Additionally, Haworth et al. discloses using incremental packing (C3/L40-53). Furthermore, Haworth

et al. discloses that the range of packing fractions be such that the inner fraction is 60-95% of that of the outer packing fraction (C3/L10-27).

- Part A has a cross sectional area extending symmetrically from a line bisecting the nozzle (form a line through the housing and from the center of the housing there is a symmetrical distribution); where this extends a substantial distance or also considered to approximately extend to the center

With respect to the "up to" limitation, it is noted that the definition of "up to" is "used as a function word to indicate a limit or a boundary", for example "up to 50000 copies a month" - See Merriam Webster dictionary definition. Thus, the phrase does not specifically require the part b region to be in contact with the opposite wall but rather that it goes in that direction but does not go past it.

The membrane occupying rate decreases along the coincident line from the nozzle to the opposite side (it decreases and then increases again - the claims do not require it to remain decreased nor do the claims preclude a subsequent increase).

With respect to $\frac{1}{4}$ or more of the cross-sectional area of the bundle, it is asserted that this limitation is met inherently. Further, no cross-sectional area has been specifically defined by Applicant. Thus, a side cross sectional area may be considered based upon a longitudinal slice.

10. Claims 1-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boivin et al. (US 2002/0079260) and further in view of Haworth et al. (USP Re. 36,125).

Regarding claims 1-2 and 11-12, Boivin et al. discloses a hollow fiber membrane (abstract) in figures 1 and 5 comprising:

- A hollow fiber membrane bundle formed of a plurality of hollow fiber membranes (1) (the bundle can also be considered rod shaped)
- A housing (2)
- An inlet (6) and an outlet (12 and 5)
- In figure 5 a membrane occupancy ratio wherein the region nearer to the inlet ports is disclosed as denser and the region away from the inlet ports is shown as less dense (see also [0023] for instance).
- The bundle of fibers has a coincident cross sectional area with that of the cylindrical housing
- Part A has a cross sectional area extending symmetrically from a line bisecting the nozzle (form a line through the housing and from the center of the housing there is a symmetrical distribution); where this extends a substantial distance or also considered to approximately extend to the center

With respect to the “up to” limitation, it is noted that the definition of “up to” is “used as a function word to indicate a limit or a boundary”, for example “up to 50000 copies a month” - See Merriam Webster dictionary definition. Thus, the phrase does not specifically require the part b region to be in contact with the opposite wall but rather that it goes in that direction but does not go past it.

The membrane occupying rate decreases along the coincident line from the nozzle to the opposite side (it decreases and then increases again - the claims do not require it to remain decreased nor do the claims preclude a subsequent increase).

With respect to $\frac{1}{4}$ or more of the cross-sectional area of the bundle, it is asserted that this limitation is met inherently. Further, no cross-sectional area has been specifically defined by Applicant. Thus, a side cross sectional area may be considered based upon a longitudinal slice.

While Boivin et al. does not explicitly set forth a PB/PA ratio of 0.5-0.95, Boivin et al. does disclose decreasing hydraulic permeability as one goes inwardly from the exterior of the fiber bundle ([0023-0025]). Furthermore, the hydraulic permeability is shown as higher in areas of more dense fibers ([0021]).

Haworth et al. discloses a mass transfer device including a hollow fiber bundle wound on a core for radially outward flow (Abstract) wherein the packing fraction of the hollow fibers increases radially outward (C3/L25-43). Additionally, Haworth et al. discloses using incremental packing (C3/L40-53). Furthermore, Haworth et al. discloses that the range of packing fractions be such that the inner fraction is 60-95% of that of the outer packing fraction (C3/L10-27).

Boivin et al. and Haworth et al. are combinable because they are concerned with the same field of endeavor, namely that of varied packing fraction hollow fiber membranes.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hollow fiber membrane structure of Boivin et al. such that the

outer most zone and the next zone in of the fibers has a relationship of packing densities such that the inner fraction is 60-95% of the outer fraction as taught by Haworth et al. for the purpose of reducing clogging near the core of the membrane.

Regarding claims 3-5, Boivin et al. further discloses multiple zones having differing packing densities, decreasing radially inwardly (see figures 6a-b). Boivin et al. further establishes various ratios between the greatest packing density and lowest packing density areas ([0020-0025]). Boivin et al. further discloses securing the membranes using adhesive bonding ([0026]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the packing density relationships to include consideration of 3 zones adjacent to each other such that only one is adjacent or neighboring the inlet and then two others non neighboring to the inlet and having a relationship of packing densities of 0.4-0.6 for the neighboring and 0.2-.04 for the non-neighboring as well as having a ratio such that the occupying rate is no more than 2 times the non-neighboring as a function of mere optimization. Furthermore, Boivin et al. establishes that these general relationships exist in ([0020-0025]) including a relationship between the packing density of the inner most and outer most being not more than 5-10. Accordingly, one having ordinary skill in the art would have known to optimize various ratios of the relationship between zones of the hollow fiber membranes by routine experimentation to achieve desired results as it has been established that the general claim conditions are present. Furthermore, Applicant has not established a criticality of the claimed ratios with regards to specific numerical values. Additionally, it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

11. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boivin et al. (US 2002/0079260) in view of Haworth et al. (USP Re. 36,125), and further in view of Misao (JP 62204804) as cited on the IDS.

Regarding claims 6 and 7, modified Boivin et al. discloses all of the claim limitations as set forth above. Boivin et al. is silent as to the use of a cylindrical current plate accommodating the hollow fiber membrane with a plurality of through holes without one at the nozzle.

Misao discloses in figures 1 and 2 a cylindrical current plate for a hollow fiber membrane with through holes (7) and a wall (8) at the inlet to prevent direct transfer of fluid (see English language abstract).

Boivin et al. and Misao are combinable because they are concerned with the same field of endeavor, namely that of hollow fiber membranes.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hollow fiber membrane of Boivin et al. to include a current plate such as the one disclosed by Misao for the purpose of preventing damage to the hollow fiber membrane by diverting the flow to avoid direct higher pressure impact to the yarns.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boivin et al. (US 2002/0079260) in view of Haworth et al. (USP Re. 36,125), and further in view of Walker (USP 5,282,966).

Regarding claim 8, modified Boivin et al. discloses all of the claim limitations as set forth above. While Boivin et al. discloses adhesive bonding the membranes ([0026]), Boivin et al. does not disclose explicitly using a material of high-polymer having a hardness of 50A-70D in a range of operating temperatures.

Walker discloses a membrane separation device (Abstract) which uses standard suitable potting materials (C10/L1-10) comprising of urethane resins and silicone resins (C10/L15-25) which inherently would have a shore hardness test of 50A-70D in a range of operating temperatures.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the membrane separator of Boivin et al. to use silicone or urethane potting resins as taught by Walker for the purpose of utilizing well known standard materials to provide a resilient, resistant to breaking potting seal. Furthermore, one having ordinary skill in the art would have chosen urethane or silicone resins over other polymer resins for the purpose of reducing costs and increasing chemical compatibility.

Response to Arguments

13. Applicant's arguments filed 3/1/2010 have been fully considered but they are not persuasive.

- Applicants continue to traverse the restriction requirement.

The Restriction Requirement was made final. The lack of unity restriction is proper as evidenced by the rejection of claims 1 and 2. A showing of lack of unity a posteriori has been made. Further, Applicant's have not shown how the method steps of claims 9 and 10 are specially adapted for the manufacture of the products of claims 1

or 2. If Applicant continues to disagree, it is suggested that Applicant consider filing a formal petition with the office of petitions for any further issues of traversal. The restriction requirement is not withdrawn.

- Applicants allege Haworth fails to show a coincident cross sectional area.

The Examiner respectfully disagrees. The claim language does not require a non-annulus shape. Further, a disc may have a hole down the center. Additionally, coincident does not imply that they must be identical shapes but rather that they are intersecting or in line.

- Applicants allege Haworth doesn't show a substantially symmetrical cross sectional area about a line coincident with the longitudinal axis and bisecting the shape and further a second region up to a side face.

This argument is not persuasive. See discussion of rejection above. Further with respect to "up to", the definition clearly shows that it is a boundary point and does not require actual contact but rather is a limit. E.g. section B cannot extend pass this point but does not have to reach this point either.

- Applicants allege Haworth fails to disclose a decreasing membrane occupying rate.

This is not persuasive. Haworth shows a decreasing occupying rate. The claim language does not preclude a subsequent increasing rate in addition to the decrease.

With respect to rod-shaped, a rod may be hollow in the center. Further, it is not claimed in claim 11.

With respect to claim 11, the first region stops at approximately the center, however, Applicant has provided no means for ascertaining and defining the needed level of precision of what entails approximately the center.

With respect to the difference between internal pressure versus external pressure hollow fiber membranes, this argument is not persuasive. Applicant has not established that there are any structural differences between the prior art and the instant claims nor has Applicant established what structure is imparted by the preamble. Additionally, Haworth makes no mention of specific features which would preclude an alternate manner of operation. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

- Applicant argues claims require high density on one side of bundle and low on the other side of the bundle.

This is not persuasive. The claims do not require this structure; see above rejections. The claims do not preclude high density on the second side.

With respect to combination of Boivin and Haworth, they are in fact combinable because both are drawn to blood treatment membrane systems.

With respect to the difference between internal pressure versus external pressure hollow fiber membranes, this argument is not persuasive. Applicant has not

established that there are any structural differences between the prior art and the instant claims nor has Applicant established what structure is imparted by the preamble. Additionally, Haworth makes no mention of specific features which would preclude an alternate manner of operation. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

With respect to Applicant's argument that changing Boivin will result in a linear gradient, this is not what is being discussed. Further, Applicant's claims do not require a linear gradient or a variation thereof. Additionally, Applicant's claims do not preclude a radial gradient.

Further with respect to internal v. external pressure, Applicant has not established any structural differences between the art and claims. Additionally, one of skill in the art would reasonably look to both variations of membrane units for teachings.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

/D. C. M./
Examiner, Art Unit 1797